

109TH CONGRESS
1ST SESSION

S. 1579

To amend the Federal Insecticide, Fungicide, and Rodenticide Act to permit the distribution and sale of certain pesticides that are registered in both the United States and another country

IN THE SENATE OF THE UNITED STATES

JULY 29, 2005

Mr. BURNS (for himself, Mr. DORGAN, Mr. JOHNSON, Mr. DAYTON, Mr. BAUCUS, and Mr. CONRAD) introduced the following bill; which was read twice and referred to the Committee on Agriculture, Nutrition, and Forestry

A BILL

To amend the Federal Insecticide, Fungicide, and Rodenticide Act to permit the distribution and sale of certain pesticides that are registered in both the United States and another country

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Pesticide Harmoni-
5 zation and Joint Labeling Act ”.

1 **SEC. 2. DEFINITIONS.**

2 (a) IN GENERAL.—Section 2 of the Federal Insecti-
3 cide, Fungicide, and Rodenticide Act (7 U.S.C. 136) is
4 amended—

5 (1) by redesignating subsections (jj) through
6 (oo) as subsections (ii) through (nn), respectively;
7 and

8 (2) by adding at the end the following:

9 “(oo) HARMONIZED COUNTRY.—The term ‘har-
10 monized country’ means a country—

11 “(1) with which the United States has entered
12 into negotiations to harmonize pesticide registration
13 regulatory processes and requirements; and

14 “(2) for which the Administrator determines, in
15 the discretion of the Administrator, that sufficient
16 regulatory harmonization has been achieved to carry
17 out joint labeling of agricultural pesticides.

18 “(pp) INTERESTED PARTY.—The term ‘interested
19 party’ means—

20 “(1) an individual producer or group of pro-
21 ducers; or

22 “(2) a nonprofit agriculture membership orga-
23 nization that represents producers.

24 “(qq) JOINT LABEL.—The term ‘joint label’ means
25 a label that—

1 “(1) has been approved for use in both the
2 United States and a harmonized country; and

3 “(2) includes a registration number of the En-
4 vironmental Protection Agency and any other license
5 number provided by a government regulatory agency
6 for the purpose of registering pesticides.

7 “(rr) JOINT REGISTRATION.—The term ‘joint reg-
8 istration’ means a product registration that—

9 “(1) has been approved by both the United
10 States and a harmonized country;

11 “(2) permits sale and distribution in both coun-
12 tries; and

13 “(3) includes a joint label.”.

14 (b) TECHNICAL AND CONFORMING AMENDMENT.—
15 The table of contents in section 1(b) of the Federal Insec-
16 ticide, Fungicide, and Rodenticide Act (7 U.S.C. prec.
17 121) is amended by adding at the end of the items relating
18 to section 2 the following:

“(hh) Nitrogen stabilizer.
 “(ii) Maintenance applicator.
 “(jj) Service technician.
 “(kk) Minor use.
 “(ll) Antimicrobial pesticide.
 “(mm) Public health pesticide.
 “(nn) Vector.
 “(oo) Harmonized country.
 “(pp) Interested party.
 “(qq) Joint label.
 “(rr) Joint registration.”.

1 **SEC. 3. JOINT LABELING OF REGISTERED PESTICIDES.**

2 (a) IN GENERAL.—Section 3(c) of the Federal Insec-
 3 ticide, Fungicide, and Rodenticide Act (7 U.S.C. 136a(c))
 4 is amended by adding at the end the following:

5 “(11) JOINT LABELING OF REGISTERED PES-
 6 TICIDES.—

7 “(A) DEFINITION OF AFFILIATE.—In this
 8 paragraph, the term ‘affiliate’ means a relation-
 9 ship among business entities in which—

10 “(i) 1 business entity—

11 “(I) has effective control over the
 12 other business entity through a part-
 13 nership or other agreement; or

14 “(II) is under common control
 15 with the other business entity by a
 16 third entity; or

17 “(ii) 1 business entity is a corporation
 18 related to another corporation as a parent
 19 to a subsidiary by an identity of stock own-
 20 ership.

1 “(B) DATE OF EFFECTIVENESS.—With re-
2 spect to joint labeling with a harmonized coun-
3 try, this paragraph shall apply on the date on
4 which the Administrator publishes in the Fed-
5 eral Register a notice that—

6 “(i) the Administrator has made the
7 finding required by section 2(o)(2) for the
8 country; and

9 “(ii) includes guidelines for interested
10 parties to petition the Administrator under
11 subparagraph (C).

12 “(C) PETITION BY INTERESTED PARTY.—
13 For an agricultural pesticide for which the
14 same or substantially similar agricultural pes-
15 ticide is registered in both the United States
16 and a harmonized country, any interested party
17 may petition the Administrator to require the
18 registrant of the agricultural pesticide to apply
19 for and use a joint label to facilitate movement
20 between the United States and the harmonized
21 country.

22 “(D) DETERMINATION BY ADMINIS-
23 TRATOR.—

24 “(i) IN GENERAL.—Not later than
25 120 days after the date of receipt of a re-

1 quest from an interested party under sub-
2 paragraph (C), the Administrator shall
3 make a determination that, in the discre-
4 tion of the Administrator—

5 “(I) the agricultural pesticide
6 registered in the United States is
7 identical or substantially similar to
8 the agricultural pesticide registered in
9 the harmonized country;

10 “(II) the registrant or affiliate is
11 the same in the United States and the
12 harmonized country; and

13 “(III) there is sufficient interest
14 from interested parties for a joint
15 label.

16 “(ii) PROVISION OF INFORMATION.—

17 “(I) IN GENERAL.—On request
18 of the Administrator, the registrant
19 shall submit information necessary for
20 the Administrator to make the deter-
21 mination described in clause (i), in-
22 cluding a product label, formula, and
23 any other information that the Ad-
24 ministrator determines, in the discre-

tion of the Administrator, may be necessary to make the determination.

“(II) DISPROVING A DETERMINATION.—In response to a determination by the Administrator under clause (i), a registrant may provide information to the Administrator to disprove a determination under subclause (I) or (II) of clause (i), including providing a confidential statement of formula to demonstrate differences between agricultural pesticides.

“(III) PROVISION OF CSF.—Notwithstanding any other provision of this Act, the Administrator may share with appropriate officials in a harmonized country a confidential statement of formula provided under subclause (II).

“(E) NOTIFICATION OF JOINT LABEL REQUIREMENT.—On making a determination under subparagraph (D) in regards to an agricultural pesticide, the Administrator shall notify the registrant that—

1 “(i) a joint label is required for the
2 agricultural pesticide; and

3 “(ii) the registrant shall propose to
4 the Administrator and the harmonized
5 country a joint label not later than 90 days
6 after notification by the Administrator.

7 “(F) REVIEW OF JOINT LABEL.—In con-
8 sultation with the harmonized country, the Ad-
9 ministrator shall—

10 “(i) review the proposed joint label;

11 “(ii) not later than 180 days after the
12 date of receipt of a proposed joint label
13 from the registrant, notify the registrant
14 that—

15 “(I) the joint label has been ap-
16 proved in the United States and shall
17 be used on all containers of the prod-
18 uct not later than a date specified by
19 the Administrator, except at the dis-
20 cretion of the Administrator; or

21 “(II) the registrant shall propose
22 to the Administrator a revised joint
23 label in accordance with guidance by
24 the Administrator as to what revisions
25 are necessary;

1 “(iii) notify the petitioner of the ap-
2 proval of the joint label and provide the pe-
3 titioner with a copy of the approved joint
4 label; and

5 “(iv) make a copy of the label avail-
6 able on the Internet, which may be used to
7 purchase and transport the approved pes-
8 ticide between the United States and the
9 harmonized country.

10 “(G) USE OF PRODUCT.—After approval
11 by the Administrator of the joint label, con-
12 sumers in the United States may obtain and
13 use the product that is registered in a har-
14 monized country, notwithstanding the fact that
15 the joint label has not been approved in the
16 harmonized country, provided that the con-
17 sumer has a copy of the joint label, as approved
18 for use in the United States.

19 “(H) SUSPENSION.—The Administrator
20 may undertake suspension proceedings regard-
21 ing registration of an agricultural pesticide in
22 accordance with the procedures described in
23 section 3(c)(2)(B)(iv) if the Administrator de-
24 termines that the registrant or affiliate—

1 “(i) within the time period required by
2 the Administrator, has failed—

3 “(I) to propose a joint label
4 under subparagraph (E)(ii);

5 “(II) to revise a joint label under
6 subparagraph (F)(ii)(II);

7 “(III) to use a joint label under
8 subparagraph (F)(ii)(I); or

9 “(IV) to provide information re-
10 quested by the Administrator under
11 subparagraph (D)(ii); or

12 “(ii) has withdrawn an application for
13 registration of a pesticide from a har-
14 monized country after receiving approval of
15 the joint label in the United States.

16 “(I) FEES.—The Administrator may not
17 charge fees for joint registration under this
18 paragraph.

19 “(J) PROHIBITION.—The joint registration
20 and labeling provisions of this paragraph may
21 not be used to add new uses to an agricultural
22 pesticide.

23 “(K) COOPERATION AND
24 PRIORITIZATION.—An interested party may pe-
25 tition the Administrator—

1 “(i) individually or in consultation
 2 with interested parties in the harmonized
 3 country; and

4 “(ii) for multiple agricultural pes-
 5 ticides at once, in priority order.

6 “(L) PRIORITY FOR REGISTRANTS.—A reg-
 7 istrant of an agricultural pesticide registered in
 8 the United States or the harmonized country
 9 that voluntarily applies for a joint label shall be
 10 given priority consideration.”.

11 (b) TECHNICAL AND CONFORMING AMENDMENT.—
 12 The table of contents in section 1(b) of the Federal Insec-
 13 ticide, Fungicide, and Rodenticide Act (7 U.S.C. prec.
 14 121) (as amended by section 2(b)) is amended by adding
 15 at the end of the items relating to section 3(c) the fol-
 16 lowing:

“(9) Labeling.

“(10) Expedited registration of pesticides.

“(11) Joint registration of registered pesticides.”.

17 **SEC. 4. JOINT REGISTRATION OF NEW PESTICIDES OR**
 18 **USES.**

19 (a) IN GENERAL.—Section 3(c)(4) of the Federal In-
 20 secticide, Fungicide, and Rodenticide Act (7 U.S.C.
 21 136a(c)(4)) is amended—

22 (1) in the first sentence, by striking “The Ad-
 23 ministrator” and inserting the following:

24 “(A) IN GENERAL.—The Administrator”;

(2) in the second sentence, by striking “The notice” and inserting the following:

“(B) COMMENT PERIOD.—The notice”;

and

(3) by adding at the end the following:

“(C) JOINT LABEL.—

“(i) IN GENERAL.—The notice shall request comments from interested parties that are interested in a joint label for the pesticide.

“(ii) DETERMINATION OF SIGNIFICANT INTEREST.—

“(I) IN GENERAL.—After the expiration of the comment period, the Administrator shall determine if there is significant interest in a joint label for the pesticide.

“(II) SIGNIFICANT INTEREST.—

If the Administrator determines that there is significant interest in a joint label for the pesticide, the Administrator shall inform the registrant that, as a condition of registering the pesticide, the registrant shall demonstrate to the satisfaction of the Ad-

1 ministrator that the registrant has
2 provided the harmonized country with
3 sufficient information for the har-
4 monized country to begin the process
5 of reviewing the application for the
6 pesticide.”.

7 (b) AUTHORITY TO REQUIRE JOINT LABEL FOR NEW
8 PESTICIDES OR USES.—

9 (1) IN GENERAL.—Section 3(c) of the Federal
10 Insecticide, Fungicide, and Rodenticide Act (7
11 U.S.C. 136a(c)) (as amended by section 3(a)) is
12 amended by adding at the end the following:

13 “(12) AUTHORITY TO REQUIRE JOINT LABEL
14 FOR NEW PESTICIDES OR USES.—After making a de-
15 termination of significant interest under section
16 3(c)(4)(C), the Administrator may notify the reg-
17 istrant that, in accordance with the procedures de-
18 scribed in subparagraphs (F), (G), (H), and (I) of
19 paragraph (11)—

20 “(A) a joint label is required for the agri-
21 cultural pesticide; and

22 “(B) the registrant shall propose to the
23 Administrator and the harmonized country a
24 joint label not later than 90 days after notifica-
25 tion by the Administrator.”.

1 (2) TECHNICAL AND CONFORMING AMEND-
 2 MENT.—The table of contents in section 1(b) of the
 3 Federal Insecticide, Fungicide, and Rodenticide Act
 4 (7 U.S.C. prec. 121) (as amended by section 3(b))
 5 is amended by adding at the end of the items relat-
 6 ing to section 3(c) the following:

 “(12) Authority to require joint label for new pesticides or
 uses.”.

7 **SEC. 5. MEMORANDUM OF UNDERSTANDING.**

8 (a) IN GENERAL.—The Administrator of the Envi-
 9 ronmental Protection Agency may enter into a memo-
 10 randum of understanding with any harmonized country to
 11 address joint registration and joint labeling procedures, as
 12 those terms are defined in section 2 of the Federal Insecti-
 13 cide, Fungicide, and Rodenticide Act (7 U.S.C. 136) (as
 14 amended by section 2).

15 (b) REQUIREMENTS.—A memorandum of under-
 16 standing entered into under this section shall address—

17 (1) sharing of information; and

18 (2) the protection of the confidential statement
 19 of formula as confidential business information.

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